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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/538,864

**Applicant(s)**

CHO ET AL.

**Examiner**

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/31/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-34, 36-38, 40-43, 77, 79-81, 83-86, 112-116, 118-120, 122, 124, 126, 128, 130, 132-136, 138-140, 142, 144, 146, 148, and 150-157 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

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### DETAILED ACTION

1. This action is written in response applicant's correspondence mailed 1/31/03. Claims 32, 40-42, 77, 83-85, 152-153, and 156-157 have been amended and claims 39 and 82 have been canceled. Claims 32-34, 36-38, 40-43, 77, 79-81, 83-86, 112-116, 118-120, 122, 124, 126, 128, 130, 132-136, 138-140, 142, 144, 146, 148, and 150-157 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is **final**.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 113, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 133, 134, 136, 138, 140, 142, 144, 146, and 148 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Ooijen et al. (US 5543576) in view of Ishiwatari *et al.* (Planta, 1995, 195(3)456-463), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Van Ooijen et al. teach transgenic plants which express genes of interest (ABSTRACT). In particular, Van Ooijen et al. teach monocot transgenic plants, specifically reciting a variety of plant types, including maize, barley, wheat, oats, rice, and grasses (Col. 6, lines 10-18). Van

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Ooijen et al. teach that the plants are useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 4, line 65-Col. 5, line 34). Van Ooijen et al. teach specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters, especially from storage genes (Col. 7, lines 58-60) and that the protein of interest should expressed in a way that allows optimal stability of the protein during seed maturation, and teach targeting to intracellular compartments (Col. 8, lines 7-10).

Van Ooijen et al. do not teach transgenic plants expressing thioredoxins.

Ishiwatari *et al.* teach the cDNA encoding a thioredoxin h polypeptide from the monocot rice (Fig. 3). Further, Ishiwatari *et al.* teach methods in which the polypeptide was over expressed in *E. coli* (p. 457).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic plants producing a monocot thioredoxin such as the one taught by Ishiwatari *et al.* using any of the routine methods taught by Van Ooijen et al. The ordinary practitioner would have been motivated by the successful expression of thioredoxins in *E. coli* by Ishiwatari *et al.*, by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Van Ooijen et al. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Van Ooijen et al. specifically teaches the advantages of such a method for the production of polypeptides stating "the present invention allows for the reduction of costs associated with the production, storage and use of a variety of enzymes (Col. 3, lines 65-67)." In the absence of a secondary consideration, such as an

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unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to rye, millet, triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of van Ooijen et al. encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Rye, millet, triticale and sorghum are such a plants, and thus the transformation of these plants is considered to be encompassed by the teachings of van Ooijen et al.

While the examiner believes that adequate motivate to make the claimed invention is provided by the above rejection, Shi *et al.* provide further motivation to make transgenic plants that produce thioredoxin h. Shi *et al.* experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Thus, the combined teachings of van Ooijen et al., Ishiwatari *et al.* and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic monocot thioredoxin h molecules. The teachings of Ishiwatari *et al.* provide a monocot thioredoxin of interest, the teachings of van Ooijen specifically provide methodology for the transformation of monocots, and Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the



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time the invention was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. The ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Ishiwatari *et al.* The ordinary practitioner would have also been motivated by the teachings of van Ooijen *et al.* to produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

Thus for all of these reasons, the rejected claims are prima facie obvious in view of the prior art.

4. Claims 32, 33, 34, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 119, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 139, 140, 142, 144, 146, and 148 rejected under 35 U.S.C. 103(a) as being unpatentable over van Ooijen *et al.* (US 5543576) in view of Gautier *et al.* (1998, European Journal of Biochemistry, 252:314-324), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Van Ooijen *et al.* teach transgenic plants which express genes of interest (ABSTRACT). In particular, Van Ooijen *et al.* teach monocot transgenic plants, specifically reciting a variety of plant types, including maize, barley, wheat, oats, rice, and grasses (Col. 6, lines 10-18). Van Ooijen *et al.* teach that the plants are useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 4, line 65-Col. 5, line 34). Van Ooijen *et al.* teach specifically teaches the production of seeds from said monocot plants, further teaching the

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use of seed specific promoters, especially from storage genes (Col. 7, lines 58-60) and that the protein of interest should be expressed in a way that allows optimal stability of the protein during seed maturation, and teach targeting to intracellular compartments (Col. 8, lines 7-10).

Van Ooijen et al. do not teach transgenic plants expressing thioredoxins.

Gautier *et al.* teach the cDNA encoding a thioredoxin h polypeptide from the monocot wheat (Fig. 1). Further, Gautier *et al.* teach methods in which the polypeptide was over expressed in *E. coli* (p. 317-318).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic plants producing a monocot thioredoxin such as the one taught by Gautier *et al.* using any of the routine methods taught by van Ooijen et al. The ordinary practitioner would have been motivated by the successful expression of thioredoxins in *E. coli* by Gautier *et al.*, by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by van Ooijen. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Van Ooijen et al. specifically teaches the advantages of such a method for the production of polypeptides stating "the present invention allows for the reduction of costs associated with the production, storage and use of a variety of enzymes (Col. 3, lines 65-67)." In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to rye, millet, triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes

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would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of van Ooijen et al. encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Rye, millet, triticale and sorghum are such a plants, and thus the transformation of these plants is considered to be encompassed by the teachings of van Ooijen et al.

While the examiner believes that adequate motivate to make the claimed invention is provided by the above rejection, Shi *et al.* provide further motivation to make transgenic plants that produce thioredoxin h. Shi *et al.* experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Thus, the combined teachings of van Ooijen et al., Gautier *et al.* and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic monocot thioredoxin h molecules. The teachings of Gautier *et al.* provide a monocot thioredoxin of interest, the teachings of Van Ooijen provide methodology for the transformation of monocots, and Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. The



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ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Gautier *et al.* The ordinary practitioner would have also been motivated by the teachings of Van Ooijen *et al.* to produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

Thus for all of these reasons, the rejected claims are prima facie obvious in view of the prior art.

5. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, and 152 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Ooijen *et al.* (US 5543576) in view of Rivera-Madrid *et al.* (PNAS USA, 92:5620-5624 (1995)), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Van Ooijen *et al.* teach transgenic plants which express genes of interest (ABSTRACT). In particular, Van Ooijen *et al.* teach monocot transgenic plants, specifically reciting a variety of plant types, including maize, barley, wheat, oats, rice, and grasses (Col. 6, lines 10-18). Van Ooijen *et al.* teach that the plants are useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 4, line 65-Col. 5, line 34). Van Ooijen *et al.* teach specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters, especially from storage genes (Col. 7, lines 58-60) and that the protein of interest should expressed in a way that allows optimal stability of the protein during seed maturation, and teach targeting to intracellular compartments (Col. 8, lines 7-10).

Van Ooijen *et al.* do not teach transgenic plants expressing thioredoxins.

Rivera-Madrid *et al.* teach five cDNAs encoding a thioredoxin h polypeptide from the *Arabidopsis thaliana* (p. 5620). Further, Rivera-Madrid *et al.* teach methods in which the polypeptide was over expressed in *E. coli* (p. 5621).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic plants producing a thioredoxin such as the one taught by Rivera-Madrid *et al.* using any of the routine methods taught by Van Ooijen *et al.* The ordinary practitioner would have been motivated by the successful expression of thioredoxins in *E. coli* by Rivera-Madrid *et al.*, by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Van Ooijen *et al.* Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Van Ooijen *et al.* specifically teaches the advantages of such a method for the production of polypeptides stating "the present invention allows for the reduction of costs associated with the production, storage and use of a variety of enzymes (Col. 3, lines 65-67)." In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to rye, millet, triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of van Ooijen *et al.* encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Rye, millet,

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triticale and sorghum are such a plants, and thus the transformation of these plants is considered to be encompassed by the teachings of van Ooijen et al.

While the examiner believes that adequate motivate to make the claimed invention is provided by the above rejection, Shi *et al.* provide further motivation to make transgenic plants that produce thioredoxin h. Shi *et al.* experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Thus, the combined teachings of van Ooijen et al., Rivera-Madrid *et al.* and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic thioredoxin h molecules. The teachings of Rivera-Madrid *et al.* provide a thioredoxin of interest, the teachings of van Ooijen specifically provide methodology for the transformation of monocots, and Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. The ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Rivera-Madrid *et al.* The ordinary practitioner would have also been motivated by the teachings of van Ooijen et al. to

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produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

Thus for all of these reasons, the rejected claims are prima facie obvious in view of the prior art.

6. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 151, and 153 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Ooijen et al. (US 5543576) in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Van Ooijen et al. teach transgenic plants which express genes of interest (ABSTRACT). In particular, Van Ooijen et al. teach monocot transgenic plants, specifically reciting a variety of plant types, including maize, barley, wheat, oats, rice, and grasses (Col. 6, lines 10-18). Van Ooijen et al. teach that the plants are useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 4, line 65-Col. 5, line 34). Van Ooijen et al. teach specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters, especially from storage genes (Col. 7, lines 58-60) and that the protein of interest should expressed in a way that allows optimal stability of the protein during seed maturation, and teach targeting to intracellular compartments (Col. 8, lines 7-10).

Van Ooijen et al. do not teach transgenic plants expressing thioredoxins.

Shi *et al.* teach nucleic acids encoding thioredoxin h polypeptides from soybean (p. 564). Shi et al. further teach experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.*

teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced monocot transgenic plants producing a thioredoxin such as the one taught by Shi *et al.* using any of the routine methods taught by Van Ooijen et al. The ordinary practitioner would have been motivated by the successful expression of thioredoxins in tobacco plants by Shi *et al.*, by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Van Ooijen et al. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Van Ooijen et al. specifically teaches the advantages of such a method for the production of polypeptides stating "the present invention allows for the reduction of costs associated with the production, storage and use of a variety of enzymes (Col. 3, lines 65-67)." In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art.

Furthermore, since Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made additional transgenic monocot plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for



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study. The ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method other plant species. The ordinary practitioner would have also been motivated by the teachings of van Ooijen et al. to produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

With regard to the claims specifically drawn to rye, millet, triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of van Ooijen et al. encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Rye, millet, triticale and sorghum are such a plants, and thus the transformation of these plants is considered to be encompassed by the teachings of van Ooijen et al. Thus, the combined teachings of van Ooijen et al. and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic thioredoxin h molecules.

Thus for all of these reasons, the rejected claims are prima facie obvious in view of the prior art.

7. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 154, and 156 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Ooijen et al. (US 5543576) in view of Brugidou et al. (Mol. Gen. Genet (1993) 238:285-293), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Van Ooijen et al. teach transgenic plants which express genes of interest (ABSTRACT). In particular, Van Ooijen et al. teach monocot transgenic plants, specifically reciting a variety of plant types, including maize, barley, wheat, oats, rice, and grasses (Col. 6, lines 10-18). Van Ooijen et al. teach that the plants are useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 4, line 65-Col. 5, line 34). Van Ooijen et al. teach specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters, especially from storage genes (Col. 7, lines 58-60) and that the protein of interest should expressed in a way that allows optimal stability of the protein during seed maturation, and teach targeting to intracellular compartments (Col. 8, lines 7-10).

Van Ooijen et al. do not teach transgenic plants expressing thioredoxins.

Brugidou *et al.* teach a cDNAs encoding a thioredoxin h polypeptide from the tobacco (p. 287 and Fig. 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic plants producing a thioredoxin such as the one taught by Brugidou *et al.* using any of the routine methods taught by Van Ooijen et al. The ordinary practitioner would have been motivated by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Van Ooijen et al. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Van Ooijen et al. specifically teaches the advantages of such a method for the production of polypeptides stating "the present invention allows for the reduction of costs associated with the production, storage and use of a variety of

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enzymes (Col. 3, lines 65-67).” In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to rye, millet, triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of experimental design. The ordinary practitioner would have recognized that the teachings of van Ooijen et al. encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Rye, millet, triticale and sorghum are such a plants, and thus the transformation of these plants is considered to be encompassed by the teachings of van Ooijen et al.

While the examiner believes that adequate motivate to make the claimed invention is provided by the above rejection, Shi *et al.* provide further motivation to make transgenic plants that produce thioredoxin h. Shi *et al.* experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Thus, the combined teachings of van Ooijen et al., Brugidou *et al.* and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic thioredoxin h molecules. The teachings of Brugidou *et al.* provide a thioredoxin of interest, the teachings of van Ooijen specifically provide methodology for the transformation of monocots, and Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants. Thus, it

would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. The ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Brugidou *et al.* The ordinary practitioner would have also been motivated by the teachings of van Ooijen *et al.* to produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

Thus for all of these reasons, the rejected claims are *prima facie* obvious in view of the prior art.

8. Claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 155 and 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Ooijen *et al.* (US 5543576) in view of Bower *et al.* (The Plant Cell, Vol. 8:1641-1650), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662).

Van Ooijen *et al.* teach transgenic plants which express genes of interest (ABSTRACT). In particular, Van Ooijen *et al.* teach monocot transgenic plants, specifically reciting a variety of plant types, including maize, barley, wheat, oats, rice, and grasses (Col. 6, lines 10-18). Van Ooijen *et al.* teach that the plants are useful for the production of any polypeptide of interest, including enzymes and industrial proteins (Col. 4, line 65-Col. 5, line 34). Van Ooijen *et al.*

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teach specifically teaches the production of seeds from said monocot plants, further teaching the use of seed specific promoters, especially from storage genes (Col. 7, lines 58-60) and that the protein of interest should be expressed in a way that allows optimal stability of the protein during seed maturation, and teach targeting to intracellular compartments (Col. 8, lines 7-10).

Van Ooijen et al. do not teach transgenic plants expressing thioredoxins.

Bower *et al.* teach two cDNA encoding a thioredoxin h polypeptide from the Brassica (p. 1462 and 1467).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced transgenic plants producing a thioredoxin such as the one taught by Bower *et al.* using any of the routine methods taught by Van Ooijen et al. The ordinary practitioner would have been motivated by a desire to produce industrially useful thioredoxin polypeptide, and by the teachings the use transgenic plants for the production of industrial enzymes as taught by Van Ooijen et al. Thioredoxins were widely known at the time the invention was made to be enzymes with many industrial uses, including in the flour making industry, as is admitted by the instant specification, and Van Ooijen et al. specifically teaches the advantages of such a method for the production of polypeptides stating "the present invention allows for the reduction of costs associated with the production, storage and use of a variety of enzymes (Col. 3, lines 65-67)." In the absence of a secondary consideration, such as an unexpected result, the instantly broadly claimed invention is free of the prior art. With regard to the claims specifically drawn to rye, millet, triticale and sorghum transgenic plants, at the time the invention was made, the selection of one of any number of plant species to be transformed for the expression of industrial enzymes would have been routine, a matter solely of



experimental design. The ordinary practitioner would have recognized that the teachings of van Ooijen et al. encompass the production of transgenic plants in any number of monocots and edible grains as discussed above. Rye, millet, triticale and sorghum are such a plants, and thus the transformation of these plants is considered to be encompassed by the teachings of van Ooijen et al.

While the examiner believes that adequate motivate to make the claimed invention is provided by the above rejection, Shi *et al.* provide further motivation to make transgenic plants that produce thioredoxin h. Shi *et al.* experiments in which they transformed tobacco plants with thioredoxin h for the purpose of studying thioredoxin h activity in plants (p. 654 and 657). Shi *et al.* further teach that thioredoxins are active in many biochemical processes in plants (p. 654). Shi *et al.* teach eight day old plants and mature plants with pods, and further teach analysis of transgenic seeds (p. 658, Col. 2). Thus, the combined teachings of van Ooijen et al., Bower *et al.* and Shi *et al.* would have further motivated the production of monocot plants expressing transgenic thioredoxin h molecules. The teachings of Bower *et al.* provide a thioredoxin of interest, the teachings of van Ooijen specifically provide methodology for the transformation of monocots, and Shi *et al.* demonstrate that the production of transgenic plants producing thioredoxin h is of interest in elucidating the functionality of thioredoxin h in plants. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made transgenic plants expressing these thioredoxin h molecules. The ordinary practitioner would have been motivated to transform transgenic plants with these molecules in order to further study the biological function of the thioredoxin h polypeptides plants, or as an alternative method for producing thioredoxin h polypeptides for study. The

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ordinary practitioner would have been motivated by the success of Shi *et al.*'s expression of thioredoxin to extend this method to the thioredoxin molecules taught by Bower *et al.* The ordinary practitioner would have also been motivated by the teachings of van Ooijen *et al.* to produce specifically monocot plants producing thioredoxin h in order to study the activity of this polypeptide in monocot plants.

Thus for all of these reasons, the rejected claims are *prima facie* obvious in view of the prior art.

9. Claims 36-37 and 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over (A) van Ooijen *et al.* in view of Ishiwatari *et al.* (Planta, 1995, 195(3)456-463), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, and 148 above, and further in view of Marris *et al.* (Plant Molecular Biology 10:359-366 (1988)) OR
- (B) as being unpatentable over van Ooijen *et al.* in view of Gautier *et al.* (1998, European Journal of Biochemistry, 252:314-324), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 119, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 139, 140, 142, 144, 146, and 148 above and further in view of Marris *et al.* (Plant Molecular Biology 10:359-366 (1988)) OR
- (C) as being unpatentable over van Ooijen *et al.* (US 5543576) in view of Rivera-Madrid *et al.* (PNAS USA, 92:5620-5624 (1995)), and optionally, both of these further in view of Shi *et al.*

(Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, and 152 above, and further in view of Marris et al. (Plant Molecular Biology 10:359-366 (1988)) OR

(D) as being unpatentable over van Ooijen et al. (US 5543576) in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 151, and 153 above, and further in view of Marris et al. (Plant Molecular Biology 10:359-366 (1988)) OR

(E) as being unpatentable over van Ooijen et al. (US 5543576) in view of Brugidou et al. (Mol. Gen. Genet (1993) 238:285-293), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 154, and 156 above, and further in view of Marris et al. (Plant Molecular Biology 10:359-366 (1988)) OR

(F) as being unpatentable over van Ooijen et al. (US 5543576) in view of Bower et al. (The Plant Cell, Vol. 8:1641-1650), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 155 and 157 above, and further in view of Marris et al. (Plant Molecular Biology 10:359-366 (1988)).

The teachings of van Ooijen et al., Ishiwatari *et al.*, Shi *et al.*, Gautier *et al.*, Rivera-Madrid et al., Bower et al., and Brugidou et al. are applied to this rejection as discussed in the previous rejections. None of these previously cited references teach the use of a barley B1 Hordein promoter. However, van Ooijen et al. do specifically teach that "Regulatory sequences which are known or are found to cause sufficiently high expression...of the recombinant DNA in seeds, can be used in the present invention...These include, but are not limited to, promoters from seed-specific genes, especially those of storage protein genes (Col. 7, lines 50-54 and 59-60)." Thus, van Ooijen et al. teach that alternative regulatory sequences can be used with their invention.

Marris et al. teach the barley B<sub>1</sub>-hordein regulatory regions localization of expressed proteins in the endosperm, and demonstrate its use to express heterologous proteins in tobacco. Marris et al. teach that "the nucleotide sequences necessary for tissue and developmental expression are present in the 549 bp 5' flanking region of the B1 hordein gene (p. 365)."

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the regulatory sequences taught by Marris *et al.* to produce transgenic plants as taught by the methods taught by any one of (A) van Ooijen et al. in view of Ishiwatari *et al.*, and optionally, both of these further in view of Shi *et al.*, (B) van Ooijen et al. in view of Gautier *et al.*, and optionally, both of these further in view of Shi *et al.*, (C) van Ooijen et al. in view of Rivera-Madrid et al., and optionally, both of these further in view of Shi *et al.*, (D) van Ooijen et al. in view of Shi *et al.*, (E) van Ooijen et al. in view of Brugidou et al., and optionally, both of these further in view of Shi *et al.*, or (F) van Ooijen et al. in view of Bower et al. and optionally, both of these further in view of Shi *et al.* The ordinary

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practitioner would have been motivated by the teachings of Marris *et al.* that the barley B1-hordein promoter drives endosperm specific expression and by the teachings of van Ooijen *et al.* that other regulatory sequences can be used in to produce transgenic plants according to their invention.

10. Claims 36, 37, 43, 79, 80, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over

(A) van Ooijen *et al.* in view of Ishiwatari *et al.* (Planta, 1995, 195(3)456-463), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, and 148 above, and further in view of Brandt *et al.* (Carlsberg Res. Commun. Vol. 50, p. 333-345 (1985)) OR

(B) as being unpatentable over van Ooijen *et al.* in view of Gautier *et al.* (1998, European Journal of Biochemistry, 252:314-324), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 119, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 139, 140, 142, 144, 146, and 148 above and further in view of Brandt *et al.* (Carlsberg Res. Commun. Vol. 50, p. 333-345 (1985)) OR

(C) as being unpatentable over van Ooijen *et al.* (US 5543576) in view of Rivera-Madrid *et al.* (PNAS USA, 92:5620-5624 (1995)), and optionally, both of these further in view of Shi *et al.* (Plant Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77, 81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138,



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140, 142, 144, 146, 148, 150, and 152 above, and further in view of Brandt et al. (Carlsberg Res.

Commun. Vol. 50, p. 333-345 (1985)) OR

(D) as being unpatentable over van Ooijen et al. (US 5543576) in view of Shi *et al.* (Plant

Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77,

81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140,

142, 144, 146, 148, 151, and 153 above, and further in view of Brandt et al. (Carlsberg Res.

Commun. Vol. 50, p. 333-345 (1985)) OR

(E) as being unpatentable over van Ooijen et al. (US 5543576) in view of Brugidou et al. (Mol.

Gen. Genet (1993) 238:285-293), and optionally, both of these further in view of Shi *et al.* (Plant

Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77,

81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140,

142, 144, 146, 148, 154, and 156 above, and further in view of Brandt et al. (Carlsberg Res.

Commun. Vol. 50, p. 333-345 (1985)) OR

(F) as being unpatentable over van Ooijen et al. (US 5543576) in view of Bower et al. (The

Plant Cell, Vol. 8:1641-1650), and optionally, both of these further in view of Shi *et al.* (Plant

Molecular Biology, 1996, 32:653-662) as applied to claims 32, 33, 34, 35, 38, 39, 40, 41, 42, 77,

81, 82, 83, 84, 85, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140,

142, 144, 146, 148, 155 and 157 above, and further in view of Brandt et al. (Carlsberg Res.

Commun. Vol. 50, p. 333-345 (1985)).

The teachings of van Ooijen et al., Ishiwatari *et al.*, Shi *et al.*, Gautier *et al.*, Rivera-Madrid et al., Bower et al., and Brugidou et al. are applied to this rejection as discussed in the previous rejections. None of these previously cited references teach the use of a barley B1

Hordein promoter or signal sequence. However, van Ooijin et al. do specifically teach that "Regulatory sequences which are known or are found to cause sufficiently high expression...of the recombinant DNA in seeds, can be used in the present invention...These include, but are not limited to, promoters from seed-specific genes, especially those of storage protein genes (Col. 7, lines 50-54 and 59-60)." Thus, van Ooijin et al. teach that alternative regulatory sequences can be used with their invention. In addition, van Ooijin et al. suggest the use of heterologous signal sequences, and teach that especially preferred signal sequences are signal sequences obtained from seed storage proteins (Col. 8, lines 17-19).

Brandt et al. teach the promoter and nucleic acid encoding the signal sequence from a B1 hordein gene from barley, which is a seed storage protein (p. 337-338; Fig. 4).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art to have modified the methods taught by any one of (A) van Ooijen et al. in view of Ishiwatari *et al.*, and optionally, both of these further in view of Shi *et al.*, (B) van Ooijen et al. in view of Gautier *et al.*, and optionally, both of these further in view of Shi *et al.*, (C) van Ooijen et al. in view of Rivera-Madrid et al., and optionally, both of these further in view of Shi *et al.*, (D) van Ooijen et al. in view of Shi *et al.*, (E) van Ooijen et al. in view of Brugidou et al., and optionally, both of these further in view of Shi *et al.*, or (F) van Ooijen et al. in view of Bower et al. and optionally, both of these further in view of Shi *et al.* by the use of the promoter and signal sequence taught by Brandt et al. The ordinary practitioner would have been motivated to have made such a modification in order to have provided an alternative methodology for the practice of the cited methods, since van Ooijen et al. clearly suggest the use of alternative regulatory sequences and signal sequence, especially from seed storage proteins.

**Response to Remarks**

The rejections under 112 1<sup>st</sup> and 2<sup>nd</sup> paragraphs are withdrawn in light of applicant's amendments to the claims.

Applicant's remarks regarding the rejections under 103 have been carefully considered but are not persuasive. Applicant's arguments are presented in groups, first addressing rejections referred to by applicant as (A)-(F) on page 11 of the arguments.

First, applicant argues that the references fail to teach all of the limitations of the claimed invention because Van Ooijen *et al.* only provide examples of seed specific expression of genes in dicot plants, and the pending claims require the seed specific expression of genes in monocot plants. This is not persuasive. Van Ooijen *et al.* specifically teach that their methods are applicable to a number of different monocot plants (Col. 6), and further teach that promoters from seed storage proteins are useful in their methods, and that for monocotyledonous plants such seed storage proteins are prolamins and glutelins (Col. 8). Applicant is reminded that MPEP 2123 teaches that "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments." In the instant case, the Van Ooijen *et al.* reference must be considered for its teaching that the methodology is useful for expressing enzymes in the seeds of monocot plants, as they specifically provide such a teaching. Applicant further suggests that the teachings of Van Ooijen *et al.* are not sufficient enablement for one of ordinary skill in the art due to "differences between dicots and monocots" but provide no evidence to support this position. Furthermore, it is noted that the instant specification teaches that the general principles of plant transformation

used in the instant methods are "standard transformation techniques" and provide a list of references to demonstrate that "successful examples of the modification of plant characteristics by transformation with cloned nucleic acid sequences are replete in the technical and scientific literature (p. 18-19 of the specification)."

Second, applicant argues that the reference fail to provide adequate motivation to combine their teachings to make the claimed invention because Van Ooijen *et al.* teach producing enzymes in seeds and thioredoxin is not an enzyme. However, this is not persuasive. The dictionary of Cell and Molecular Biology-Online! defines thioredoxin as "Intercellular disulphide-reducing enzyme (printout of definition attached)." Furthermore, Brugidou *et al.* (of record) state "Thioredoxins are small, ubiquitous oxidoreductase proteins. The fact that they are oxidoreductase proteins means that they are enzymes (i.e. an oxidoreductase is an enzyme). Applicant further argues that Van Ooijen *et al.* actually teach away from using plants to overproduce non-enzyme proteins. However, the teaching cited by Van Ooijen *et al.* is a portion of their specification wherein they discuss the deficiencies of the prior art relative to their invention. This is not a teaching away, even if thioredoxin were not an enzyme. The motivation to combine the references is clearly provided in the rejections, which state that the practitioner would have been motivated to produce the economically useful thioredoxin in seeds, or to further study the effects of the thioredoxin expression on the transformed monocot plants.

Third, applicant argues that the prior art provides no reasonable expectation of success to combine their teachings. Absolute predictability is not required in order to establish an expectation of success. The MPEP states, "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no

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reasonable expectation of success may support a conclusion of nonobviousness (2143.02)."

Applicant provides no further reasoning to support this argument, other than again stating that thioredoxin is not an enzyme, and Van Ooijen *et al.* do not exemplify the transformation of enzymes. As previously discussed, thioredoxin is an enzyme, and Van Ooijen *et al.* clearly suggest the transformation of monocot plants. Arguments of counsel are not found to be persuasive in the absence of a factual showing. MPEP 716.01(c) makes clear that

"The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant."

Finally, applicant argues that even if a proper prima facie case of obviousness has been established that the case is fully rebutted the unexpected results provided in the specification. The MPEP states that "the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range (MPEP 716.02(d))." In the instant case, the unexpected results demonstrated in the specification are not commensurate in scope with the instantly rejected claims. The specification demonstrates that barely expressing wheat thioredoxin h under the control of a seed specific promoter have accelerated germination, and increased activity of alpha amylase and pullulanase in the seeds. Furthermore, the specification demonstrates that wheat plants overexpressing wheat thioredoxin h and Arabidopsis NTR have increased digestibility and reduced allergenicity. However, although both wheat and barley are monocot plants, these results are not sufficient to overcome the rejections applied herein, because the claims are not commensurate in scope with the unexpected results. Applicant has



provided no evidence or reasoning that either of the two different unexpected results observed would be applicable to the genus of all monocot plants or all monocot thioredoxin h molecules. With regard to the unexpected result observed in transgenic wheat plants, this was observed in plants that were transformed with both wheat thioredoxin h and Arabidopsis NTR. There is no showing that such an unexpected result would even be observed in wheat plants overexpressing only wheat thioredoxin h.

Applicant also makes reference to an "unexpected result" with regard to sorghum plants expressing barley thioredoxin h. However, it is noted that example 6 of the specification which discusses such a plant is prophetic, and provides no results, therefore, provides no unexpected result.

Applicant further provides arguments with directed towards a next set of rejections identified on page 14 of the response as (G)-(L), in each of these rejections Marris *et al.* are cited. Applicant merely reiterates the previously set forth arguments and state that Marris *et al.* fail to overcome the supposed deficiencies of the previous rejection. These arguments have been addressed.

Applicant further provides arguments with directed towards a next set of rejections identified on page 15-16 of the response as (M)-(R), in each of these rejections Brandt *et al.* are cited. Applicant merely reiterates the previously set forth arguments and state that Brandt *et al.* fail to overcome the supposed deficiencies of the previous rejection. Applicant reiterates the argument that the previously cited references fail to teach a seed or grain maturation-specific promoter in monocot plants. This argument has been addressed. Applicant further argues that Brandt *et al.* fail to teach the promoter or the signal sequence of the B-1 hordein gene from

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barley, and that they fail to create transgenic plants utilizing the promoter. This is not persuasive because Brandt *et al.* teach the signal sequence for the protein (p. 337, Col. 1) and also the sequence of the promoter region of the barley hordein gene. Combined with the teachings of the other prior art references cited (i.e. the suggestion by Van Ooijen *et al.* to utilize such sequences to produce monocot transgenic plants), the ordinary practitioner would have arrived at the claimed invention. Applicant's arguments against Brandt *et al.* alone is essentially an impermissible piecemeal analysis. Again, applicant suggests that the combined references would have no expectation of success but provides no evidence to support the suggestion. Applicant's further argument with regard to rejections (M)-(R), have been previously addressed.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Thursday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.



JEFFREY FREDMAN  
PRIMARY EXAMINER



Juliet C. Switzer  
Patent Examiner  
AU 1634

April 29, 2003

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

U.S. Patent and Trademark Office  
PTO-326 (Rev. 04-01)

**Office Action Summary**

Part of Paper No. 0403

Continuation of Disposition of Claims: Claims pending in the application are 32-34,36-38,40-43,77,79-81,83-86,112-116,118-120,122,124,126,128,130,132-136,138-140,142,144,146,148 and 150-157.